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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,444	02/10/2004	Thomas A. Berson	009103-016030US	3698

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EXAMINER
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KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/776,444

Applicant(s)

BERSON ET AL.

Examiner

Matthew J Kremer

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/10/04</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1 and 5 are objected to because of the following informalities. In claim 1, line 3, "and" should be inserted after "characteristic;". Claim 5 recites the limitation "said data" in line 5 in which there is insufficient antecedent basis. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,942,877 to Sakai et al. (Sakai)(cited by Applicant). Saiki teaches a pulse oximeter sensor 1 and a memory 56. (Fig. 1 of Sakai). It is noted that the limitation "said memory containing data relating to said sensor and containing a digital signature" was not given any patentable weight since this limitation related only to a data structure contained in the memory. In other words, the memory only contains 0's and 1's and nothing in the claimed invention provides meaning to those 0's and 1's. Therefore, the data stored in the memory of the claimed invention is not distinguishable from the data

stored in the memory of Sakai since both sets of data are merely 0's and 1's in a structural sense. In regard to claims 2-4, the limitations in those claims are attempting to narrow the scope of the data stored in the memory of the claimed invention but, as stated above, the particular data stored in the memory of the claimed invention is not distinguishable from the data stored in the memory of Sakai since the data in the memory of Sakai and the data in the claimed invention are both merely 0's and 1's in a structural sense.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 16, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,995,855 to Kiani et al. (Kiani)(cited by Applicant) in view of U.S. Patent 5,987,343 to Kinast (cited by Applicant).

In regard to claims 1 and 16, Kiani teaches an oximeter sensor 402 and an adapter with information element reader 1420. (Fig. 14 of Kiani). Kiani further teaches that the array 1420 is a predetermined set of different information elements that correspond to the possible sensors that the monitor 404 accepts. (column 14, lines 20-22 of Kiani). Kinast teaches an EEPROM memory is one such information element.

(Abstract and Fig. 2 of Kinast). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the memory of Kinast in the adaptor of Kiani since Kinai teaches that a predetermined set of different information elements are used and Kinast teaches one such information element. It is noted that the limitation "said memory containing data relating to said sensor and containing a digital signature" was not given any patentable weight since this limitation related only to a data structure contained in the memory. In other words, the memory only contains 0's and 1's and nothing in the claimed invention provides meaning to those 0's and 1's. Therefore, the data stored in the memory of the claimed invention is not distinguishable from the data stored in the memory of Sakai since both sets of data are merely 0's and 1's in a structural sense.

In regard to claim 19, Kiani teaches an oximeter sensor 402 and an adapter with information element reader 1420. (Fig. 14 of Kiani). Kiani further teaches that the array 1420 is a predetermined set of different information elements that correspond to the possible sensors that the monitor 404 accepts. (column 14, lines 20-22 of Kiani). Kinast teaches an EEPROM memory is one such information element. (Abstract and Fig. 2 of Kinast). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the memory of Kinast in the adaptor of Kiani since Kinai teaches that a predetermined set of different information elements are used and Kinast teaches one such information element. It is noted that the limitation "said memory containing sensor data and containing a digital signature" was not given any patentable weight since this limitation related only to a data structure contained in the

memory. In other words, the memory only contains 0's and 1's and nothing in the claimed invention provides meaning to those 0's and 1's. Therefore, the data stored in the memory of the claimed invention is not distinguishable from the data stored in the memory of Sakai since both sets of data are merely 0's and 1's in a structural sense. In regard to claim 20, Kiani teaches an internal monitor and a conditioning circuit. (Fig. 10 of Kiani).

6. Claims 1-6, 8-12, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO 97/29678 to Osadchy et al. (Osadchy) (cited by Applicant) in view of U.S. Patent 5,817,009 to Rosenheimer et al. (Rosenheimer) (cited by Applicant), and further in view of U.S. Patent 5,987,343 to Kinast (cited by Applicant). Osadchy teaches a microcircuit in a catheter connector, which has a calibration code. The code is encrypted using an RSA encryption scheme using a public key and a private key. (page 6, lines 18-31 of Osadchy). The catheter provides the physiological signal and the microcircuit has that calibration code which is data relating to the catheter and contains a digital signature in the form of the RSA encryption scheme. Osadchy does not teach that the smart sensor is applied to pulse oximeters. Osadchy teaches that the distal end of the catheter can be used for performing electrophysical measurements. (page 11, lines 34-37 of Osadchy). Osadchy further teaches that the calibration data can be used for physiological sensors in the catheter. (page 22, lines 20-22 of Osadchy). It is well known in the art that pulse oximeters are types of physiological sensors that are placed on catheters. (column 3,

lines 21-25 of Rosenheimer). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pulse oximeter sensor of Rosenheimer on the catheter of Osadchy since Osadchy teaches physiological sensors can be used and Rosenheimer teaches one such sensor. Osadchy teaches that the calibration data of the physiological sensor is stored in the catheter. (page 22, lines 20-23 of Osadchy). It is well known in the art of pulse oximetry that memory units on the probe are used to store calibration data since it is desirable to know several parameters of a particular sensor, such as wavelength error, LED intensity, and sensor type. (column 2, lines 13-24 of Kinast). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the calibration data on the probe as disclosed by Kinast since Osadchy teaches that calibration data of the physiological sensor can be stored on the catheter and it is desirable to know several parameters of the particular sensor, such as wavelength error, LED intensity, and sensor type. In regard to claims 9-12 and 15, the combination teaches the use of a housing (Fig. 1 of Osadchy); the use of sensor inputs, processing circuits, and processing circuits (Fig. 5 and page 12, lines 10-20 of Osadchy; column 1, lines 20-31 of Osadchy; and Fig. 2 of Kinast); and the use of sensor reader memories (page 6, lines 7-31 of Osadchy).

7. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO 97/29678 to Osadchy et al. (Osadchy) (cited by Applicant) in view of U.S. Patent 5,817,009 to Rosenheimer et al. (Rosenheimer)

(cited by Applicant), and further in view of U.S. Patent 5,987,343 to Kinast (cited by Applicant) as applied to claims 5 and 9, and further in view U.S. Patent 6,307,938 to Matyas, Jr. et al. (Matyas)(cited by Applicant). The combination does not teach the use of the Rabin-Williams signature. Osadchy teaches that any public key encryption/decryption methods known in the art may be used. (page 6, lines 27-29 of Osadchy). Osadchy further teaches that RSA algorithms can be used. (page 6, lines 27-29 Osadchy). Matyas teaches that the RSA method and Rabin-Williams public key algorithms are known. (column 10, lines 54-62 of Matyas). Both methods are public key cryptographic algorithms, which perform the same tasks and are functionally equivalent. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the Rabin-Williams method for the RSA method of Osadchy since they are functionally equivalent and Osadchy teaches any known public key encryption/decryption or digital signature methods can be employed.

8. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO 97/29678 to Osadchy et al. (Osadchy) (cited by Applicant) in view of U.S. Patent 5,817,009 to Rosenheimer et al. (Rosenheimer) (cited by Applicant), and further in view of U.S. Patent 5,987,343 to Kinast (cited by Applicant) as applied to claims 5 and 15, and further in view of U.S. Patent 5,995,855 to Kiani et al. (Kiani)(cited by Applicant). The combination does not teach that the memory associated with the sensor is mounted in an adapter coupled between the sensor and monitor. Kiani teaches that calibration circuitry relating to the sensor can be placed in



an adapter so that different sensors can be used with different monitors (see column 14, lines 20-22 of Kiani). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the memory in an adapter as disclosed in Kiani since this allows different sensors to be used with different monitors.

9. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,298,255 to Cordero et al. (Cordero). Cordero teaches a sensor system which includes a biopotential signal monitor, a smart sensor and the accompanying hardware and software interface which authenticates the source and validity of the smart sensor and also verifies that the smart sensor meets various criteria for use. (Abstract of Cordero). Cordero et al. does not explicitly state that the smart sensor is applied to pulse oximeters but Cordero teaches that the invention is related to electrophysiological sensors. (column 1, lines 9-12 of Cordero). Cordero further teaches four related patents that disclosed coded sensors in oximeters. (column 1, line 59 to column 2, line 32 of Cordero). Cordero implies that these devices would be improved by using the smart sensor configuration to store specific data concerning the sensor itself, the date of expiration, sensor serial number, calibration data, and configuration data. (column 3, lines 6-20 of Cordero). From this information, one with ordinary skill in the art would conclude that the smart sensor configuration is applicable to oximeters. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the smart sensor configuration in an oximeter since Cordero implies that oximeters would benefit from such a configuration. In regard to claims 1 and 7,

digital signature algorithms such as El Gamal and RSA public key encryption algorithms can be used. (column 17, lines 35-55 of Cordero). In regards to claim 2 and 6, the source of the smart sensor 2 is authenticated and the integrity of its data validated by using a "digital signature." Signature generation requires the use of a "hash" function (h). In the case of a public key algorithm, the digital signature is generated using a signature generation function which typically uses both the private and public keys as well as the hashed message. (column 15, line 63 to column 16, line 37 of Cordero).

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 4, 5, 8, and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, and 20 of U.S. Patent No. 6,708,049 to Berson et al. (Berson). Although the conflicting claims are not identical, they are not patentably distinct from each other. In regard to claim 1 of the present application, claim 1 of Berson claims a "pulse oximeter apparatus comprising: a

pulse oximeter sensor having an output for providing a signal corresponding to a measured physiological characteristic; a memory associated with the sensor and located external to a monitor which receives the sensor signal, said memory containing data relating to said sensor and containing a digital signature". Claim 1 of Berson claims an apparatus, which is narrower in scope than claim 1 of the present application. Claim 1 of Berson meets all the limitations set out in claim 1 of the present application and it would be obvious that the apparatus of claim 1 of Berson is actually the apparatus of claim 1 of the present application. In regard to claim 4 of the present application, claim 1 of Berson claims "wherein at least a first portion of said data is contained within said digital signature".

In regard to claim 5, claim 10 of Berson claims a "method for creating a digital signature in a pulse oximeter apparatus including a memory associated with a pulse oximeter sensor having an output for providing a signal corresponding to a measured physiological characteristic, said method comprising: signing at least a portion of data relating to said sensor to create a digital signature; storing said digital signature in said memory; storing data relating to said sensor in said memory". Claim 10 of Berson claims a method, which is narrower in scope than claim 5 of the present application. Claim 10 of Berson meets all the limitations set out in claim 5 of the present application and it would be obvious that the method of claim 10 of Berson is actually the method of claim 5 of the present application. In regard to claim 8, claim 10 of Berson claims a "second digest contained within the digital signature", which is narrower in scope than "imbedding at least a portion of said data [relating to said sensor] in said digital

signature” since the digest is more particular than just a portion of data related to the sensor. Claim 10 of Berson claims a method, which is narrower in scope than claim 8 of the present application. Claim 10 of Berson meets all the limitations set out in claim 8 of the present application and it would be obvious that the method of claim 10 of Berson is actually the method of claim 8 of the present application.

In regard to claim 15 of the present application, claim 20 of Berson claims a “system comprising: (a) a sensor apparatus including a sensor, said sensor having an output for providing a signal corresponding to a measured physiological characteristic, and a sensor memory associated with said sensor, said sensor memory having digital data relating to said sensor and having a digital signature, said digital signature being a signature of at least a portion of said data...and (b) a sensor reader including a sensor reader housing; a sensor input for receiving said signal from said sensor corresponding to a measured physiological characteristic; a sensor processing circuit coupled to said sensor input; a memory input for receiving said digital data from said sensor memory; a first sensor reader memory coupled to said memory input for storing said digital data; a second sensor reader memory storing a signature verification key; and a third sensor reader memory storing a program for verifying said digital signature using said signature verification key”. It is noted that claim 15 of the present application uses the limitations a “pulse oximeter system”, a “pulse oximeter sensor apparatus” and a “pulse oximeter sensor reader” while claim 20 of Berson claims a “system”, a “sensor apparatus”, and a “sensor reader”. However, despite the change in the labels, the claimed elements for the sensor apparatus and the sensor reader in Berson are narrower in scope than the

claimed elements for the pulse oximeter sensor apparatus and the pulse oximeter sensor reader in the present application. It is the listing of these elements that define the scope of the sensor reader and the sensor apparatus for both of these claims and not just the labels themselves. Thus, claim 20 of Berson is narrower in scope overall than claim 15 of the present application. Claim 20 of Berson meets all the limitations set out in claim 15 of the present application and it would be obvious that the system of claim 20 of Berson is actually the system of claim 15 of the present application.

12. Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. U.S. Patent No. 6,708,049 to Berson et al. (Berson) in view of U.S. Patent 4,942,877 to Sakai et al. (Sakai)(cited by Applicant). In regard to claim 9, claim 19 of Berson claims a "sensor reader comprising: a housing; a sensor input for receiving a signal from a sensor corresponding to a measured physiological characteristic; a sensor processing circuit coupled to said sensor input; a memory input for receiving digital data stored in a memory associated with said sensor, said digital data including a digital signature; a first sensor reader memory coupled to said memory input for storing said digital data; a second sensor reader memory storing a signature verification key; a third sensor reader memory storing a program for verifying the digital signature of said digital data using said signature verification key...and a transfer circuit for providing at least a portion of said digital data to said sensor processing circuit". Claim 19 of Berson does not claim a particular kind of physiological sensor. Sakai teaches a pulse oximeter that would fall

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within the scope of a physiological sensor as set forth in claim 19 of Berson. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pulse oximeter of Sakai in the claimed invention of Berson since Berson claims a physiological sensor and Sakai teaches one such physiological sensor.

### ***Response to Arguments***

13. Applicant's arguments filed 2/10/2004 have been fully considered but they are not persuasive. The Applicant has argued that the inventors would not have been motivated to look in the wireless catheter prior art for solutions to the pulse oximeter problems of the increased danger of uncertified sensors and potential for errors. However, the Examiner has not argued the motivation that there was a pulse oximeter problem and one would be motivated to look in wireless catheter technology to solve this problem. As provided in the rejection above, one with ordinary skill in the catheter technology was motivated to look into various medical sensors since Osadchy teaches that the distal end of the catheter can be used for performing electrophysical measurements. (page 11, lines 34-37 of Osadchy). It is well known in the art that pulse oximeters are types of physiological sensors that are placed on catheters. (column 3, lines 21-25 of Rosenheimer). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pulse oximeter sensor of Rosenheimer on the catheter of Osadchy since Osadchy teaches physiological sensors can be used and Rosenheimer teaches one such sensor. The

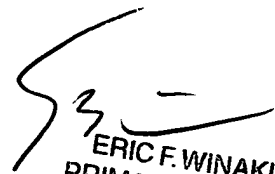
Applicant's argument is, therefore, not relevant since the Examiner has not used the motivation suggested by the Applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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